K042478

SEP 17 2004

HITACHI

HITACHI MEDICAL SYSTEMS AMERICA, INC.
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510(k) Summary

Submitter Information

Submitter: Hitachi Medical Systems America, Inc.
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Contact: Douglas J. Thistlethwaite

Date: June 11, 2004

Device Name

Device Name:	Computed tomography x-ray system, Emission computed tomography system
Trade/Proprietary Name:	SceptreP3
Common Name:	Computed Tomography X-ray System, Emission computed tomography system
Classification Name:	System, X-Ray, Tomography, Computed
	System, Tomography, Emission Computed
Classification Number:	Sec. 892.1750
	Sec. 892.1200

Predicate Devices

Predicate Devices:	Presto CT	Hitachi Medical	K040902
	ECAT EMERGE PET	CTI PET Systems	K003241
	PET/CT Patient Handling System (PHS)	CTI PET Systems	K023768
	Sceptre-VS (AVIA) Workstation	Hitachi Medical	K021314

Device Description

Introduction

The SceptreP3 combines the technologies of a multi-slice x-ray computed tomography system, an LSO positron emission computed tomography scanner, and a DICOM compliant image workstation into an integrated system that uses the PET and CT data to produce cross-sectional images of the body at various angles.

The system is made up of 4 discrete sub-systems that are independently marketed under unique 510(k) clearances. The sub-system models are:

Sub-System	Model	Manufacturer	510(k)
CT	Presto	Hitachi Medical	K040902
PET	ECAT ART-LSO PET System	CTI PET Systems (CPS)	K003241
Workstation	Sceptre-VS (AVIA)	Hitachi Medical	K021314
Patient Table	PET/CT Patient Handling System (PHS)	CTI PET Systems (CPS)	K023768

Scientific Concepts

The CT sub-system uses "third generation" CT technology, where the x-ray tube and detector assemblies are mounted on a frame that rotates continuously around the patient using slip ring technology. The solid-state detector assembly design collects up to 4 slices of data simultaneously. The x-ray sub-system features a high frequency generator, x-ray tube, and collimation system that produces a fan beam x-ray output. The system can operate in a helical (spiral) scan mode where the patient table moves during scanning. As the x-ray tube/detector assembly rotates around the patient, data is collected at multiple angles. The collected data is then reconstructed into cross-sectional images by a high-speed reconstruction sub-system.

The PET sub-system uses partial ring LSO detector technology, where the detectors rotate around the patient and collect emission data from the injected radiopharmaceutical.

The computer workstation (AVIA™) initiates data acquisition and processes the resultant images. The images are stored, printed, and archived as required. CT data is used to create attenuation correction maps for the PET images as well as for standard CT image display. The workstation is also capable of fusing CT and PET images into one display to show both anatomical and physiological data. The workstation is based on current PC technology using the Windows™ operating system.

Physical and Performance Characteristics

The SceptreP3 system consisting of a CT gantry, a PET gantry, operator's workstation, patient handling system (table), high-frequency x-ray generator, and accessories. The system performance is identical to the predicate devices.

Performance Comparison

Because the SceptreP3 simply combines freestanding CT and PET systems, its performance mirrors the predicate devices. There are no fundamental performance changes to the CT and PET sub-systems, nor the image workstation. The only change allows the workstation to the control PET data collection, request motion of the PHS and to automatically receive the image data from the CT and PET sub-systems.

The evaluation results of the SceptreP3 are comparable to the predicate devices and support our conclusion that the Sceptre PET/CT system is substantially equivalent.

Device Intended Use

The SceptreP3 system is intended to be used:

1) to produce cross-sectional images of the human body that measure the distribution of positron emitting radiopharmaceuticals within the imaged area,
2) to produce cross-sectional images of the body produced by x-ray transmission from the same axial plane taken at different angles,
3) to create attenuation maps from the x-ray data to correct the PET images, and
4) to combine (co-register) the CT and PET images after reconstruction to produce images with both anatomical and physiological data.

The system processes, displays, and stores the reconstructed images. The device output can provide an aid to diagnosis when used by a qualified physician.

Device Technological Characteristics

The CT and PET sub-system are functionally identical to their predicate devices. Physically, the SceptreP3 combines the two gantries under one cover and uses a new patient table, called a Patient Handling System (PHS). The PHS is identical to the predicate PHS device.

The operation of the system is virtually identical to the predicates because the operating software on the CT and PET subsystems is largely unchanged. The key differences are the ability to initiate PET data collection and control the PHS from the AVIA workstation. This necessitated minor changes to the CT and PET sub-systems to allow them to accept commands from the AVIA. The PHS design allows the table pallet to extend through the CT aperture into the PET aperture. Gantry controls provide the same features as the CT predicate, but the control layout was modified to accommodate the new covers.

Despite these differences, the SceptreP3 system is technologically equivalent in concept, function, and performance to the predicate devices.

Conclusions

The SceptreP3 system has been developed and validated according to applicable standards. Testing has proven that the system is safe and effective for the indicated use. Risk and hazard analysis shows that there are no new safety issues associated with this system as compared with the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2004

Hitachi Medical Systems America, Inc.
% Mr. Daniel W. Lehtonen
Staff Engineer-Medical Devices
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K042428
Trade/Device Name: SceptreP3 PET/CT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 90 KPS and JAK
Dated: September 7, 2004
Received: September 8, 2004

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K042428

Device Name: SceptreP3 PET/CT System

Indications for Use:

The SceptreP3 system is intended to be used:

1) to produce cross-sectional images of the human body that measure the distribution of positron emitting radiopharmaceuticals within the imaged area,
2) to produce cross-sectional images of the body produced by x-ray transmission from the same axial plane taken at different angles,
3) to create attenuation maps from the x-ray data to correct the PET images, and
4) to combine (co-register) the CT and PET images after reconstruction to produce images with both anatomical and physiological data.

The system processes, displays, and stores the reconstructed images. The device output can provide an aid to diagnosis when used by a qualified physician.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyerly

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042428

Prescription Use ✓ OR Over-the-Counter Use _____